EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
OF THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	)	Master File No. 2:12-MD-02327 MDL 2327
CHERYL BERDEN, Plaintiff, vs. ETHICON, INC., ET AL. Defendants.	)	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE Civil Action No. 2:14-CV-21966

--- This is the Deposition of VLADIMIR IAKOVLEV, M.D. taken at the law offices of Blake, Cassels & Graydon, 199 Bay Street, Suite 4000, Toronto, Ontario, Canada on the 11th day of September, 2018.

REPORTED BY: JUDITH M. CAPUTO, RPR, CSR, CRR

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I N D E X

WITNESS: VLADIMIR IAKOVLEV, M.D.

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-- Upon commencing at 1:10 p.m.

VLADIMIR IAKOVLEV: AFFIRMED.
DIRECT EXAMINATION BY MR. SNOWDEN:

Q. Good afternoon, Dr. Iakovlev.
A. Good afternoon.
Q. We are here to discuss your opinions in the Cheryl Berden case; is that your understanding?
A. Yes, it is.
Q. All right. And did you bring a flash drive with you today with your case-specific materials?
A. I did.
Q. All right. Let's take a look at that, please. Thank you.
Does that flash drive contain all of your case-specific materials that you're relying upon with the exception of the specimens in this case?
A. Yes, as for previous cases, I included all records I received, chain of custody forms of the specimen I received incoming and outgoing, and my billing for this case.
There may be some pictures,

case-specific pictures, which I believe you already have, like from Suncoast Pathology. So I did not include them.
Q. Okay. Are there any case-specific materials other than the specimens in this case and potentially some photographs that you'll be relying on that are not on the flash drive?
A. Not that I'm aware of.
Q. And it looks like the flash drive contains chain of custody forms, some medical records and an invoice; is that right?
A. Yes.
Q. And the invoice is dated June 23, 2018; is that right?
A. Yeah, probably.
Q. And it's in the amount of $15,237.50; is that right?
A. Yes, that's right.
Q. And is that total the fee for all of your work in this case?
A. Does it include supplemental report?
Q. It does.
A. Yes, so it is.
Q. And it looks like you did an

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initial report and then on June 23rd, you billed an additional $5,462.50 for a supplemental report?
A. Yes, that is right.
Q. Do you have any plans to do any additional work in this case?
A. Not at this point. I mean, if I receive more specimens or I receive more materials then I may, but I don't plan to do anything at this point.
Q. All right.
MR. SNOWDEN: Let's go ahead and mark as Exhibit 1 your case-specific report for Ms. Berden.
EXHIBIT NO. 1: Expert Report - Clinico-Pathological Correlation of Complications Experienced by Cheryl Berden dated June 4, 2018.
BY MR. SNOWDEN:
Q. And Dr. Iakovlev, does Exhibit No. 1 contain all of your case-specific opinions outside of the supplemental report in this case?
A. Yes, it does. I mean, up-to-date, unless I have new information or new specimen.
Q. Let's mark as Exhibit 2 your supplemental report in this case.

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EXHIBIT NO. 2: Supplemental Expert Report - Clinico-Pathological Correlation of Complications Experienced by Cheryl Berden dated June 23, 2018.
BY MR. SNOWDEN:
Q. And is Exhibit No. 2 a complete copy of your supplemental report regarding Ms. Berden?
A. Yes, it is.
Q. Okay. And let's mark as Exhibit 3 the flash drive.
EXHIBIT NO. 3: Flash Drive containing Documents Reviewed by Dr. Iakovlev.
BY MR. SNOWDEN:
Q. Looking at Exhibit 1, it is dated June 4, 2018, and is that right?
A. Which page is it?
Q. It's on page 28.
A. Yes, it is.
Q. All right. And then flipping to Exhibit No. 2, I think the date on that is June 23, 2018, page 12; do you see that?
A. Yes.
Q. So in this case, you did your

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case-specific findings for Ms. Berden before issuing a supplemental report that contains general topics regarding Mersilene; is that correct?
A. That's correct.
Q. What was the reason for doing it in that order?
A. No specific reason. Because there was a deadline to submit case-specific report. Most of this information in the supplemental report is elsewhere in some other reports, maybe not for Ethicon litigation, for something else.
Some of it was in other reports; some of it was not in other reports. But generally, I was aware of the issue and then I just put it in formal sort of reports, put them into a report.
Not that I didn't know about all these issues. I mean, I knew about these issues. I learn about these issues for the last five years, just being involved in mesh research.
Q. How many Mersilene specimens have you reviewed in your practice?
A. I had several of explanted multifilament polyester meshes because most of them came through, or I think all of them came through -- all except this one -- came through just regular

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diagnostic work from surgeons. They were all hernia specimens.
I don't think I ever had Mersilene mesh used for sacropexy. This is the first case.
How many of those were Mersilene? It's hard to say, because when it's a diagnostic sample, there's no sticker and sometimes you cannot trace what it was.
It is polyester and it is multifilament. I would say less than ten, maybe ten, somewhere in that range.
Q. Okay.
A. But it's just an estimate. I never counted them.
Q. And of those less than ten Mersilene meshes that you've reviewed, how many did you review microscopically?
A. All of them. I always review all meshes microscopically. I take sections from each specimen.
Q. Was the mesh from Ms. Berden the first Mersilene that you reviewed for legal purposes?
A. Yes, it is.
Q. Okay. Have you since reviewed any

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other Mersilene mesh for legal purposes?
A. No.
Q. Okay. Have you performed any research specifically targeting Mersilene mesh?
A. Those hernia specimens, or hernia mesh explants which were polyester multifilament meshes, they were -- they are in the group, in the same group, when I analyze samples.
I did not specifically focus, but I keep track of them, that they're either multifilament or monofilament.
When I measure, for example, those parameters you're aware of like nerve density or degree of foreign body type reaction, I measure it for multifilament meshes as well, but I keep track that it's multifilament not monofilament.
So it's part of the same project, but there is no focus on multifilament yet. When I analyze the data, then I start comparing them and see if there's any difference.
Q. Have you published any of your results regarding Mersilene mesh?
A. No, I think all published -- all publications were limited to monofilament designs. I have data, I keep analysis, but it just happened

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that we limited, we focused on monofilament designs because they're more prevalent.
Q. Have you performed any chemical testing on any of those Mersilene meshes?
A. Well, the chemical testing I do is the same as for anything else. We use stains, we stain and see how tissues behave under different stains.
If they absorb, if it becomes stains, that's a chemical testing. I did not do any sort of material science type of testing like FTIR or something else, because that's not what I do. It's not part of pathology.
Q. So is it fair to say any review of those meshes was limited to routine pathological analysis, and potentially viewing it under polarized light microscopy?
A. Always polarize them. But, yeah, the methods for routine diagnostic methods of any laboratory.
Q. Have you, outside of your review of Mersilene mesh under the microscope, have you authored any publications that involve Mersilene mesh?
A. Not specifically focused on

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Mersilene mesh, no.
Q. Is it fair to say the focus of your work so far on implantable mesh has been focused on polypropylene?
A. Yes, because it's over 90 percent of all meshes on the market now.
Q. For the supplemental report that you issued in this case, was it your idea to do a supplemental report?
A. I don't remember exactly whose idea at first. I felt that I need to provide extra information, because it's a new mesh, never specifically focused on it.
I knew that I cannot put it together before the deadline. I knew the issues but I needed to put it formally, put the references in order and other things.
So I needed more time. And the only way to do it was to issue a supplemental report.
So we decided to split: First case-specific opinions and then whatever general opinions I needed came in the supplemental report.
Q. Is it fair to say that the supplemental report focuses on mesh exposure with Mersilene and infection with Mersilene?

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A. This is the main issue with multifilament meshes. It focuses on it because that, that's what I find different from monofilament designs.
It will have the same nerves growing into the larger pores; it will have the same scarring. But the features which separate it from monofilament is multifilament design.
There's not even difference between polyester and polypropylene; it's mostly multifilament design. That's different and that introduces additional risks, and the risks are erosion and especially infection.
So that's why I focused on this, because I focused on the differences with monofilament designs, which have been discussed extensively over the last five years.
Q. If we step back for a moment and think about what your -- the total opinions you have in this case, we have a general report that you did involving polypropylene meshes and other mesh issues, which I think you first said in wave one.
You have your Berden case-specific report and your supplemental report; is that fair?

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A. Which is focusing on differences between Mersilene and monofilament polypropylene meshes.

Q. I just want to make sure there are no other reports out there; is that it?

A. Yes, that's it.

Q. All right. I notice in this report, and speaking about the supplemental report, you cited to 65 mostly articles; is that fair?

A. Yes, 65 references.

Q. References?

A. Uhm-hmm.

Q. Do these references form the basis of your opinion, opinions that are found within the supplemental report?

A. They provide information from published literature. Again, it's not limited to this list because I have a long list which had been served for wave cases, being global sort of analysis, which is over 700 publications.

But these are references for specific features which were described in the general report -- in the supplemental report.

Just to support specific, sort of not conclusions, but descriptions which were found in

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the published literature.

Q. Is it fair to say that for the statements that you make in this report, the pertinent literature that supports your statements is found in the list at the end of the report?

A. Yes, directly pertinent with literature to the statements in the report, yes. But there is background knowledge which is supported by the global list.

Q. Have you reviewed any internal company documents regarding Mersilene?

A. Not that I remember.

Q. Have you asked for any?

A. I don't think so, not that I remember.

Q. And have you reviewed any depositions of Ethicon employees regarding Mersilene mesh?

A. No.

Q. Have you asked for any of those?

A. No.

Q. With regard to vaginal mesh erosion, is it your opinion that monofilament mesh is an improvement over multifilament mesh?

A. In terms of infection,

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monofilament mesh is better than multifilament.

Erosion is somewhat a sort of gray zone. Again, if there is more chances for infection, there will be more chances for erosion. Because erosion can be primary event or secondary event. Sometimes we just don't know what is chicken and what is egg.

Q. If we can turn to your supplemental report, Exhibit 2. On the second page of the report, you note in the first paragraph that mesh-specific factors play a role in secondary types of erosions; is that true?

A. Yes.

Q. What factors play a role?

A. So it's been found that more solid materials, like solid silicon strips, which don't allow tissue ingrowth, like no tissue ingrowth at all, so that's a factor.

So the more tissue ingrowths through the mesh, the less chances of erosion.

So then we can move from microporous to macroporous. So the same, if we compare macroporous with microporous materials like EPTFE, again, EPTFE will have higher rates of erosion -- or tendency for erosion is higher.

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So even if it's the same material, but different structure of a mesh, again, microporous will introduce extra risks for erosion than macroporous.

Then the size of the devices. The larger the device generally is the higher risks for erosion.

Q. Any other specific factors that play a role?

A. So it would be type of material, porosity, micro versus macro, size.

Q. Does the type of material matter?

A. Type of material matters, but usually there is a connection between the design porosity and the type of material.

For example, EPTFE will always be microporous, unless you start punching big holes in it, and then it would become class 3.

But if you compare different materials with identical or very similar mesh structure, for example, multifilament polypropylene versus multifilament polyester, they will introduce the exactly same risks.

For example, like polyester multifilament versus polypropylene multifilament,

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because the difference with monofilament is the spaces in between filaments, and then it doesn't matter as much as the material itself.

Although if material starts degrading and cracking, it will introduce its own. But if it was pristine, brand new, there will be no difference, or no significant difference that I can appreciate or I am aware of.

Q. You have in here, after your citations at number 7, you have:

"Comparatively, meshes made out of the same material, polypropylene both different pore size show an advantage to larger pore designs."

Do you see that?

A. I do.

Q. What do you consider here as the larger pore designs?

A. So, for example, if we take ObTape, Mentor product and that was class 3, was mostly microporous rather than macroporous. And compare it with macroporous, or larger pore designs like TVT or similar products, ObTape showed much higher risks for erosion and infection.

Not that TVT is immune to that, but, I

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mean, the multifilament design or -- class 3 design immediately showed higher complication rates. Because it may take much longer for TVT to develop erosions and so forth, but for ObTapes, I mean, really quickly within a year or two (indicating).

So movement from multifilament to monofilament designs usually give you larger pores in entire structure.

Q. In the next paragraph, your first sentence you state that the risks of -- I'm skipping the first part of the sentence -- The risks of mucosal erosion are dependent on design". Do you see that? The first sentence of the paragraph?

A. Yes, I got it.

Q. Is that essentially just a restatement of what we just discussed in terms of the specific factors?

A. Yes. I mean, this is more like a summary sentence. It could have been last sentence in the previous paragraph. For whatever reason, I chose it to be the first sentence in the second paragraph.

Q. Okay. And your cited basis here is several articles which involve inhaled material,

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wood, shunt catheters, interocular implants, and microsutures; is that right?

A. Oh, I would have to see what's in those publications.

Q. Let's take number -- so the first one is slings. Sorry, I forgot to mention slings.

MR. HAIL: It's page 13.

THE WITNESS: Okay.

BY MR. SNOWDEN:

Q. You'd agree at least in Ms. Berden's case -- I'm going to jump from case-specific for just a second -- we're not talking about a sling in Ms. Berden's case; is that fair?

A. Yeah, it is fair, but it's mesh.

Q. And then if we look at number ten here -- sorry, I'm quoting the wrong sentence.

MR. SNOWDEN: Can we go off the record for a second?

-- OFF THE RECORD DISCUSSION --

BY MR. SNOWDEN:

Q. All right, Dr. Iakovlev, let me redirect you here.

The next sentence talks about that objects become exposed because they do not become

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integral physiological tissue component.

Do you see that sentence?

A. Yes, I do.

Q. "They remain a foreign body, they can damage the tissues, interrupt healing and is targeted for destruction, encapsulation and expelling."

Do you see that?

A. I do.

Q. Okay. And now you cite your basis for support here, at least the cited basis is numbers 14 through 19 from your literature list; is that fair?

A. Yes. But, see, this sentence is not specific to meshes now. This sentence is describing our general knowledge that foreign objects can move through the tissue, can damage the tissue, it can become exposed.

This is not specific for any type of foreign object; any foreign object can do it.

Q. And so, I think you'll then agree with me that numbers 14 through 19 do not involve any type of mesh; is that fair?

A. Yes, I mean that was the purpose,

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just to show that this was normally -- in 1960, '82, '88, I mean, these are earlier publications just show to background knowledge of how foreign objects behave in the body.

Q. In preparation of your supplemental report, did you undertake or review the literature involving Mersilene mesh?

A. I did.

Q. And what were you looking for?

A. I put keyword "Mersilene" and searched what is available, what's -- specifically I was paying more attention to infection, because the case is about infection.

But I was searching for anything which was available, specifically for Mersilene. So I have an open mind, but I had a focus for a specific case for Ms. Berden as well.

Q. Are there any studies pertinent to your opinions in this case that are not included on the materials list for your supplemental report?

A. I'm not sure. I mean, I included everything I thought was relevant -- oh, directly relevant to the supplemental report.

If there were any other studies which I saw that they describe Mersilene mesh, it could be.

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But if they are not relevant directly, like they didn't describe sacropexy, or if they didn't -- for whatever reason I thought that they are not directly relevant. There could be other studies, yes.

Q. So you've reviewed studies that form sort of a basis of background knowledge, but in terms of the studies that you really -- the pertinent studies you really rely on for your supplemental report, are found in your supplemental report; is that fair?

A. Yes, because my focus was generally to search for Mersilene but at the same time pay more attention to sacropexy or Mersilene used for sacropexy and the complications or infections related to Mersilene mesh.

Q. As part of that review, was your aim to determine the overall rate of erosion and infection with Mersilene mesh?

A. No, I don't think you can do that. It's very difficult to do, in terms of pinpointing exact rate of erosion. And you need to do very long studies. And in her case, it took, I think three years for her to develop the complications.

So the studies should be much longer.

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To me, she might just be falling in the middle, so I have to do 6 or 10 years. In some other meshes which I have seen in my practice, they became infected eight years, I believe. So it's sometimes it gets infected much later.

So unless we have studies which follow these patients for 10, 15 years, we may never even estimate what are the true complication rates.

Q. Did you, in your literature search, did you locate any reviews that attempted to state overall complication rates that you rejected and did not include in your report?

A. No, I did not -- I was not focusing on specific complication rates. This is not my focus. I see that most studies are short, they don't provide -- I mean, as I said, unless it's a very long study, I wouldn't trust these numbers. The fact that it can do it, the fact that the complication exists is sufficient.

Trying to aim at specific complication rates, I think it might be misleading. Just because there is no good quality data, not because it will not provide any extra information, but it's better not to use low quality data, just use either positive or negative sort of binary approach.

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Either it can do it or it cannot do it.

In general, we know that this type of designs, multifilament designs, they have higher rates of complications and that's why they are classified separately. But this is a general background knowledge.

Q. Hypothetically speaking, if the data showed one patient out of 1,000 experience complication, is that sufficient for you to render a general opinion that the device can cause that complication?

A. If we ask about specific ability, or ability of a device to cause a complication, one patient or one study, I mean, that they can provide, it will also -- obviously if there is a series of patients or like a small series, instead of case report, value is much higher, and prospective studies are even higher.

So the quality of data will increase. One single case report, comparing with series and then retrospective studies, and then prospective studies, it will be higher. But the highest quality would be prospective studies lasting 10 to 15 years.

Q. This question is obvious to me

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now, but I'll ask it anyway. Are you offering any opinion about the overall risk of infection or a version of Mersilene?

A. I don't offer opinion for specific numbers. I offer an opinion that the risks are higher than for monofilament designs.

Q. When you say monofilament design, is that all monofilament designs, including all types of materials?

A. In general, class 1. Macroporous, but monofilament designs will all be macroporous.

It may be variable, it can be somewhat different designs or devices, but overall, class 3 meshes have higher risks of infection than class 1.

Q. When you were reviewing the incidence of infection with Mersilene mesh, were you making any distinction between where it was implanted?

A. You mean in the supplemental report?

Q. In the supplemental report?

A. It depends where we discuss it. For example, if we discuss it specifically for sacropexy mesh, it's implanted where the sacropexy mesh is.

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The classification was designed for hernia meshes; we know that. It wasn't designed for sacropexy meshes.

And the classification was based on previous studies showing -- specifically focusing on ingrowth -- tissue ingrowth and infection, but it was all hernia meshes.

Q. So in terms of when you're looking at the literature in this for your supplemental report, and determining the incidence of infection with Mersilene, did you make any distinction between papers that showed the rate in hernia mesh, versus mesh implanted with abdominal sacral colpopexy, versus other types of mesh?

A. So, as I said, the numbers can be very -- the range of numbers can be quite broad depending on quality of data and follow up time and so on.

If we have a number, it means it cannot drop below that because these old flaws in the study, they will lead to underestimation. It is very hard to have a flaw in the study which will overestimate.

But all deficiencies in the studies, especially short follow up, will lead to

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underestimation. So we can see what is the minimum number, but it will be hard to compare between different studies.

As I said, overall, all evidence shows that multifilament meshes will have higher complication rates. This knowledge comes from different publications, from earlier publications, and that's why it was based -- basis for the classification.

Does that answer your question?

Q. I'm not sure, but we'll move on.

A. Okay.

Q. So the same question for your literature review regarding erosion, did you limit -- strike that.

So with regard to literature review for erosion as a complication, did it matter to you whether the description was for a hernia mesh, versus a pelvic mesh, versus some other type of mesh?

A. Well, hernia mesh rarely erodes. So the erosions, I mean -- let's see what specifically is there.

(Witness reviews document).

So in terms of erosion, as I earlier

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mentioned that erosion can be a secondary event or primary event.

So erosion can come first, and then infection. Or, infection can come first and then it will lead to erosion. Sometimes it's almost impossible to distinguish.

In the study which I analyzed, they had both complications, erosion and infection. But, as I said, in this specific location, a mesh can lead to an erosion.

For hernia meshes, when the mesh is buried deeper down, there is corrosion; it's small. If there is an erosion it's usually chronic sinus formation from infected mesh.

And vaginal location, either for transvaginal placement or through abdominal placement, the risk of erosion. But we cannot state or we don't know if it is primary erosion or secondary erosion. The conclusion of that study was that better material is needed to avoid erosion rates.

I don't think I can compare many studies, specifically for erosion rates, just because we don't have good quality data.

But in this specific publication, it

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was shown that it is at least 5.5 percent and I estimate that it may double or triple if you do followup, sufficiently long followup.

Q. And we'll talk about that study in a little bit.

You mentioned in your report, on page 3, that reports of infection associated with monofilament mesh, Mersilene, date back to at least the 1970s; do you see that?

A. Yes.

Q. And at the end of your report, you conclude that Mersilene mesh -- strike that.

Would you agree that Mersilene mesh has been used for decades?

A. Yes, for hernia surgery, in low volumes and in the end it became classified as class 3 and was not -- as we all know, it's not a preferred choice for surgeries. Either hernia or vaginal surgeries.

Q. And the risk of infection with Mersilene mesh has been known since at least the 1960s; is that fair? Sorry, 1970s; is that fair?

A. There were reports and at the time the use of mesh was in very low volumes, there were sporadic reports. From what I understand, the

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information was there, but it was not organized in sort of clean classification.

The time when it was verbally sort of established and put into a square box of classification, it was by Amid in the '90s.

So we don't know how exactly many people were aware, we don't know what's -- the information was out there, but how widespread that knowledge was, we don't know.

Q. Okay.

A. By '90s I could say every surgeon should be aware, or at least have some, or source where to learn it.

Q. And then if I understand the conclusion here, or the concluding page of your report, it's your opinion that the use of Mersilene has declined significantly since the 1990s; is that fair?

A. My opinion is, or at least from what I see in the number of publications, the interest declined. So the number of publications declined.

I don't know the numbers they use. It may stay the same, it could have dropped, but interest, in terms of scientific interest, dropped,

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declined. Usually it means the uses has declined.

Q. Is it your opinion that's the result of the knowledge of the risk of infection?

A. I think it's combination, if people understand that they bring specific risks, they may not be sold by as many companies, surgeons may not buy them or don't use them.

I mean, there are multiple factors around -- if there are more superior materials and more superior designs, people prefer others. Both ends, manufacturers and users.

Q. Okay. And in terms of the risk of erosion for Mersilene mesh, I ask the same questions. Is it the same answer?

A. For?

Q. For the risk of erosion with Mersilene mesh? Was it well-known after 1997?

A. Well, it was a very low volume of news, as I understand it. It wasn't a large volume, and there was not that many publications.

In the specific publications which are referenced it is clearly described in there, because it's not -- there is no large volume of literature on sacropexy meshes or Mersilene used for sacropexy.

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It was never used in large volumes and there was no large volume literature.

Q. Do you know if Mersilene sutures are used at St. Michael's Hospital?

A. You mean polyester multifilament? I mean, there may be Ethibond. It's not Mersilene per se, but polyester multifilament.

Q. Let's start first with Mersilene suture.

A. I do not know if it's specifically Mersilene, but they use multifilament polyester sutures, yes.

Q. Do you know if Mersilene mesh is used at St. Michael's Hospital?

A. I have seen it only explanted. I have never seen one used as a primary repair.

Again, I receive specimens when something goes wrong. I'm not aware of what surgeons are using. My understanding was mostly these other designs.

Q. Have you ever warned anyone at St. Michael's Hospital that they shouldn't be using Mersilene?

A. What conversations I had? There was one excision and a surgeon asked me what I see.

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And I said, well, it looks different.
This was one of the first experiences was multifilament design. I said, it looks different. It's not monofilament; what it can be?
I said it can be Mersilene, I remember at that time specifically Mersilene.
And he said, it could be, but I thought -- that's what he said. He said, "I thought nobody is using multifilament designs anymore". So that was impression of an experienced surgeon.
I think by now he retired, but he's been in practice a long time. So he was a bit surprised that there are still multifilament meshes out there.
So to answer your question, it's not me who advised but it was the surgeons who actually told me that they are surprised that somebody is still using it.
Q. Do you recall who that was?
A. It was an older surgeon. He retired. I don't remember now.
Q. Have you ever told anyone at St. Michael's that Mersilene was harming the patients?
A. No, I didn't. Again, because when I was talking to surgeons, I understood that they

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know more about it than me. So, I mean, who am I to teach them if they already know better than me?
And then when you go to conferences and you mention multifilament designs, and everybody say, infection. Infection, infection, infection.
Q. How long have you been hearing that at conferences?
A. Since I first started going to the hernia conferences, I mean. I think it was in -- sorry, 2013, 2014, somewhere in there. Again, I was introduced in this field starting from 2012.
But the conferences are for surgeons, and surgeons have been in this field for decades. Some have been practicing for 40 years. They saw all of these meshes coming and going.
Q. At the end of your report, end of your supplemental report, you have a chart or a graph in your -- in the body of the report; do you see that?
A. On page 12.
Q. On page 12, yes?
A. Yes.
Q. What is the purpose for including this?
A. Just to show the dangerous

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decline. Or if -- I've used it for many other keywords, like vaginal mesh. You may have seen my report which is using the same approach.
So you just put a keyword and then you see what's interest, when the interest appears.
It's interesting because then you see after introduction of the device on the market, then there's a spike, then enthusiasm drops a little bit but the use stays stable or drops a little bit.
So you can have some idea what's interest for researchers and what's the use of the devices.
And for most publications, for most keywords, this curve goes up. Because world population grows, number of researchers grows, and so for pretty much any -- most of keywords, the number of publications goes up.
But for Mersilene it dropped. Or at least it didn't go up. It was an increase beginning from '60s, which reflects natural evolution of things to '90s. But then after '90s it didn't go higher.
And classification for type 3 devices -- oh. Mesh classification came about somewhere in

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the '90s. So after '90s, there's no increase.
Q. So what conclusions are you drawing from this data for purposes of Mersilene?
A. There is no conclusion. I'm just demonstrating that the design didn't take off, didn't become prevalent neither in practice nor in research?
Q. And what is it basis for being able to make the association between the numbers of publications and what you state on your report that, "Experiences and knowledge affected use and introduction of new multifilament designs"?
A. No new designs. Or, at least, the newer designs were not multifilament designs.
So, okay.
"The above described experiences and knowledge affected use and introduction of new multifilament mesh designs. For example, in published literature, an annual number of publications using the keyword Mersilene listed on PubMed declined significantly since the 1990s."
So I know I'm aware that no other

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multifilament designs were introduced, either. So that's why I'm saying it affected new multifilament designs.

The only multifilament mesh design which was introduced for vaginal surgery was ObTape, which was withdrawn from the market. And which showed higher complication rates. That's it.

Since then, there were no multifilament mesh, as I am aware of, on the market for vaginal surgeries.

Q. My question is a little bit different.

I guess, where did you get the idea and that's what I mean by the basis. What's the basis for saying, I can look at the number of times something is mentioned on PubMed and that is associated with the interest and use of a product?

A. Oh, it's just one of the indicators. It's not direct connection, it's one of the indicators.

I see that no new multifilament designs were offered. I mean, all devices for monofilament designs -- there was only one design I am aware of offered for slings. It didn't last for long.

When you search for Mersilene, it's not

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going up. The number of -- the interest is not -- appears not to be increasing.

So everything started revolving around monofilament designs, which have their own drawbacks, of course.

Q. Do you know who Dan Corlan is?

A. No.

Q. It's his website, right?

A. Yeah, yes. I mean, you can probably do it through other search engines, but I found this website is easy to use. You just enter a keyword and you get the numbers.

Q. Do you know what his background is?

A. No, I don't.

Q. Did you validate the methodology that that website uses?

A. No.

Q. Did you read the warning on the website about the use of the data?

A. There could be some warnings, yes. I don't remember now.

Q. So you don't remember:

"WARNING: Counting papers with a given feature is a very gross

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bibliometric method. Sometimes the results are relevant, sometimes they require extensive checking, but they must always be interpreted very carefully"?

A. That's what I would say as well. As I said, this is one of the indicators, one way of showing -- and I said, there is a decline and if we question the validity of the search, at least there is no increase.

But we also know by other factors that the design didn't take off. So if there's nothing, there is nothing new.

This information can be presented in multiple different ways. I chose this because it's a graph, which is easy to see. But everybody knows that Mersilene is not and has never been a prevalent design. The interest never took off.

Q. Have you ever entered polypropylene into the -- into that web page?

A. Yes. Polypropylene, vaginal mesh, hernia mesh, hernia polypropylene. I did multiple searches. As I said, some of the graphs are in my other reports.

And you can trace, it's relatively

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accurate. You can trace the number of publication spikes after introduction of the device, and then there is a dip after FDA warning, or it can reflect different other -- for example, specific introduction, specific surgeries.

So whatever the drawbacks of these websites are, from what I have seen it follows the historical events relatively well.

Q. Have you ever put your name in there?

A. No.

Q. I have to tell you there's a dip.

MR. SNOWDEN: Go off the record. Can we take just a quick break?

-- RECESS TAKEN AT 2:08 --

-- UPON RESUMING AT 2:11 --

BY MR. SNOWDEN:

Q. All right, Doctor. I want to ask you about the supplemental report beginning on page 8, and it's my understanding from my review -- strike that.

If you go to page 8 of your supplemental report and specifically talking about where it begins, "The earliest attempts" and then beyond that. What is the purpose of this portion

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of your report?
MR. HAIL: Objection to form.
THE WITNESS: So the initial portion, or initial part is describing classification and relevance of classification for Mersilene design, or how the Mersilene mesh, and why it became class 3.
And then from page 8, I'm focusing on Mersilene mesh for pelvic surgeries. So this is from general sort of multifilament design, more focusing to multifilament design used in pelvic surgeries.
BY MR. SNOWDEN:
Q. In that paragraph beginning, "The earliest attempts to use multifilament mesh" on page 8; do you see that?
A. I do.
Q. Okay. The next sentence: "Among other" -- sorry after that one:
"Later, erosions, infection and formation of chronic sinus reported in the 1990s for Mersilene mesh used for pelvic prolapse surgeries."
Do you see that?

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A. I do.
Q. And for that you've cited to two articles; is that correct?
A. Yes.
Q. And then you go on to say that:
"This procedure is not recommended as a primary procedure for the repair of anterior vaginal segment."
Do you see that?
A. I do. I just copied that sentence from publication.
Q. Why did you include this quoted portion of that paper?
A. Because I saw it as relevant.
Q. How is it relevant?
A. Well, it's a conclusion of the researchers who researched that specific type of mesh and for pelvic surgeries.
You can go to that paper and see the overall, it was a scope of the paper. But those researchers concluded what they concluded.
Q. Were their conclusions significant to your opinions in this case?
A. My opinions were formed based on

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many pieces of information. I can't say that one piece of information was more significant than the others. So bit by bit, each source of information was providing more information to form my opinions.
How significant it was, I can see that in these publications, they describe the erosions, infection, formation of chronic sinus. So it's at least there is an example that the design can result in this complications.
Q. And I think we've covered this before, but does it matter to you how many women were involved in the studies that are cited there?
A. I mean, obviously the larger the number, the better quality, the better quality of data.
But you can go only by what you have. If there is no large volume of literature, whatever is available is available.
As I said, that my opinions were formed using multiple sources of information. Some had more information, some had better quality of information, some less.
Q. And how would you assess the quality of the information in number 45, the paper by Creighton?

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A. I would have to see the publication. And there's no scale, I don't think I can put a scale on it from 1 to 10. And generally, there will be better and lower quality but I don't think we can scale them.
Q. Is it your practice to include papers you find to be of poor quality in your report?
A. As I said, sometimes you just go by what you have. I'm not the researcher. I'm just researching published literature and trying to find information.
So any source of information can be useful, but then I cannot control what the quality of the data is there.
When there is a large volume, when there are 500 publications, you have luxury of picking or trying to assess what's the difference, whether the better quality papers, whether the lower quality papers, you still pay attention to all of them. But then you have more choices.
Q. And you included, if I understand your testimony, you included the number 46 because it was relevant to the Mersilene device; is that fair?

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A. I would have to see the publication exactly. But that was a Mersilene mesh used, as far as I understand from the text. So we can put -- I mean, you probably have it printed, so it would be useful for me to have it in front of me.

Q. And then continuing in that paragraph, you state that more data were accumulated by 2000; do you see that?

A. Yes.

Q. And in this study, it says it's a larger study that followed 273 patients; do you see that?

A. I do.

Q. Do you recall how many of those 273 patients had been implanted with Mersilene mesh?

A. I think all except four; that's my recollection. Again, if we discuss a paper I would like to have it in front of me.

Q. Mark this as Exhibit 4, please.

EXHIBIT NO. 4: Article Entitled, "Vaginal Mesh Erosion After Abdominal Sacral Colpopexy" by A. Visco, et al.

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BY MR. SNOWDEN:

Q. And Doctor, is Exhibit 4 the paper that you cite at number 47 in your materials list for your supplemental report?

A. Yes, it is.

Q. Okay. Counsel can correct me if I'm wrong, but Ms. Berden was implanted with Mersilene mesh with an abdominal sacral colpopexy; is that your understanding?

A. Yes, it is.

Q. In the Visco paper, we'll call number 47 the Visco paper since that's the first author. It looks like they discuss the vaginal mesh erosion after an abdominal sacral colpopexy; is that correct?

A. So they had several types of surgeries.

Q. They had an abdominal sacral colpopexy, which is what Ms. Berden had, correct?

A. Yes.

Q. Abdominal sacral colpoperineopexy?

A. -- perineopexy, yes.

Q. And, two combined vaginal and abdominal colpoperineopexy groups; is that true?

A. Yes, that is my understanding.

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Q. Okay. And of those two, one with vaginal suture passage, and the other with vaginal mesh placement, correct? It's on the first page under "Study Design".

A. Are you reading -- sorry. I was in the text, in the body.

(Witness reviews document).

Q. Third line down under "Study Design"?

A. So four groups: Abdominal sacral colpopexy, abdominal sacral colpoperineopexy and two combined vaginal and abdominal colpoperineopexy groups.

Q. Would you agree that Ms. Berden, if she were in this study, she would have fallen into the abdominal sacral colpopexy group; is that fair?

A. Well, you would have to check with the urogynecologist. I mean, because there might be some nuances between the surgeries.

I mean, overall, the focus of this study was sacropexy procedures using Mersilene mesh. Most of them were done by Mersilene mesh and Ms. Berden falls in this overall group.

There is some differences within that

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group, and I think it would be better to ask the urogynecologist to see exactly where nuances is.

But overall, to me, this study is an example of a study of sacropexy procedures using mostly Mersilene mesh.

Q. Okay. And in your report, you cite the reported overall erosion rate of 5.5 percent, correct?

A. Overall for all procedures, yes. Again, we can discuss the quality of that number with degree of possible underestimation, but at the time when they stopped the study that was the number overall.

Q. Is there any particular reason you didn't include the rates for the -- each individual group in the study?

A. No. No specific reason. Because there might be some variations within -- because once you start splitting a larger group into smaller subgroups, your quality of data drops.

Why? Because you have smaller groups. In those smaller groups there can be shorter followup time.

For whatever reason, this procedure, this specific procedure came about with one

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publication, or new surgeon came. So that procedure could have been started only later on. So the follow up would be shorter than for other groups.

So, I mean, to me, the general rule of thumb in research is, first, you aim at the larger group, sort of that will give you overall better quality of data, although it will not be a specific, but quality of data will be large.

Once you start splitting, you have to be careful because you may have very large variation in the quality of data due to specific reasons as I mentioned.

Q. Is that the reason you didn't consider the 3.2 percent mesh erosion rate for abdominal sacral colpopexy group?

A. That was one of the reasons.

Q. What are the other reasons?

A. Because, first of all, I didn't want to include smaller groups, because they will have larger variation.

Some rates are as high as 16 and 40 percent. So I didn't want to choose specific groups, as I mentioned, because of the large variation.

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And you can see the spread, from 3.2 to 40 percent. It is a huge spread. 5.5 percent is more representative of an entire approach.

And if there are differences between the groups, they may or may not be true differences. They may be differences due to factors like I mentioned. New surgeons came in, new procedure became in fashion, specific time point.

Q. Do you see that the abdominal sacral colpopexy group had the majority of the study participants in this study at 155?

A. Yes, it was a larger group.

Q. Do you know any of the authors of this publication?

A. No, I don't.

Q. Do you know if they're professors at Duke?

A. Well, I can see that it's coming from Duke -- well, Durham, North Carolina, that's Duke University.

Q. Is that a respected institution?

A. As far as I know it is.

Q. Did you find this publication of enough quality for you to include it and rely upon

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it in your report?

A. Again, enough to be included. Not that it is the only source of information or the main source of information.

It's information. It's a source of information for Mersilene mesh used for sacropexy, which is closer to what Ms. Berden had. Or just overall, use of Mersilene mesh for pelvic surgeries.

Q. On the next page, you say, page 9 in the middle of the page:

"Considering that, statistically medians closely represent 50th percentile, the lifelong rates would be expected more than to double with sufficiently long follow up time."

Do you see that?

A. I do.

Q. What does that mean?

A. So if we check the median followup for the entire study was 5.8 times -- sorry, I'm a little tired.

So median length of follow up was 5.8 month for the entire study. And then, the median

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number of month to appearance of mesh erosion was 15.6 month. And then 12 month for different, and later 9-month.

So each group had range. But all those ranges, or most of them, were at least double or -- were at least double or triple of the median followup time.

So if you think about it, if it takes, for example, anywhere between 4 to 15 month to develop a complication, and the longest will be 15.6 month to develop a complication for specific patients, and your study only is limited to 5 months or 6 months, any time shorter than the median appearance of median time to appear -- I'm tired.

MR. HAIL: Do you want to take a break?

THE WITNESS: Yes, a short break.

MR. SNOWDEN: Usually not in the middle of an answer but it's fine.

MR. HAIL: He can finish.

-- RECESS TAKEN AT 2:30 --

-- UPON RESUMING AT 2:32 --

THE WITNESS: So the answer is that the followup of entire study was significantly shorter, or median followup of entire study was shorter than

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the median time for -- until appearance of erosions.

Therefore, the study just didn't follow patients long enough to catch complications. And it was severely shorter. It's not something -- I expect they didn't detect half of the complications.

BY MR. SNOWDEN:

Q. How are you able to determine the number of complications they didn't detect, if they didn't detect them?

A. Well, if it's median time for followup, and then median time for complication, for timing of complications, this is roughly 50th percentile.

So, for example, the largest group, which is abdominal only sacropexy, you just mentioned that it was largest group.

Their median time until appearanced erosion was 15.6 month. And overall study was, median time for overall study was 5.8 month, but specifically for abdominal sacral colpopexy, the same group, 6.5 month.

So the study was only half long as it takes for the complications to appear, even

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shorter. Because 6.5 months time two will be 13 month. But it takes 15 month for complications to appear, for median number.

So 50 percent of complications are expected to appear within 15 month, and then another 50 percent will appear after 15.6 months. But this is an estimate, again, because the study didn't go far enough. So it likely, even 15.6 is an underestimation.

Q. Is there any accepted method of estimating the complications that were not reported in the study, as you've done?

A. I'm not estimating, I'm just estimating how much -- I'm just analyzing the median follow ups. There's no estimation. I don't know by how much they are underestimating. It can be double or triple, just based on the numbers.

Again, there is no exact estimation, but there's obvious underreporting. And the degree of underreporting can be times, times two or times three.

Q. Are you able to say to a reasonable degree of medical certainty what the degree of missed complications was in the study?

A. To a reasonable degree of medical

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certainty, my opinion would be severe underestimation.

Q. Okay. Are you able to then estimate the -- what the true percentage of complications should have been in this study?

A. No, you cannot. You have to follow the patients for 30 years. This study was cut short, therefore, they only scratch the surface.

And based on their numbers, it shows that the study severely underestimates overall risk of complications.

Q. Is it fair to say that you're using the study to provide a floor for the erosion rate with Mersilene?

A. No, I'm not using it to provide a floor. I can tell you that if you ask me what that number may mean, I can tell you that it's likely minimum complications. But I would not use it as a floor.

Because if you go longer, then you will reach another floor. If you follow them even longer, you will reach another floor. It will be a continuous process again. So even for the floor, it will be dependent on length of studies. I don't

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expect it to drop lower than 5.5.

Q. Okay. Are you basing your opinions on any other studies that show a better representation of the erosion rate for Mersilene mesh?

A. I'm not aware of long-term studies, of sufficiently long-term studies, something like 15 or 20 years. I'm not aware of those, I have not found them. Sufficiently large and sufficiently long.

It has to be focused, it has to be large, because there's no point of reporting all complications for 2 or 3 patients. So it has to be prospective, long, large study. And that's what I was looking for, I couldn't find it.

Q. You'd also agree that reporting 1 or 2 complications in a small number of patients is problematic?

MR. HAIL: Objection. Argumentative.

THE WITNESS: What do you mean "problematic"?

BY MR. SNOWDEN:

Q. Well, okay. Can you read back his last answer, not the question but the last answer.

-- Reporter's Note: Whereupon, the

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question was read as recorded above.
THE WITNESS: Yes, what I meant, I wouldn't take into consideration, or would consider them but I wouldn't take them as a high-quality data if there is a study for 2 or 3 patients.
You can report them. I mean, it gives you some information. But you have to understand it's low-quality data.
BY MR. SNOWDEN:
Q. Okay. Would you also agree that a study with a small number of patients that has 1 or 2 complications can skew the data into showing a higher incidence than the true incidence of the complications?
A. Either higher or low. Because low quality data means that it's not very accurate; that's what it means.
Q. When you mentioned "large" before, how many patients are you talking about when you say large?
A. The larger the better. This group is not bad. I mean, again, I cannot put a scale to it. But, I mean, this study is relatively large. I think it was -- how many overall? 273 patients. So it gives you a representation, a good

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representation.
Q. Okay. If we can turn to the next page of your report, page 10.
A. Yes.
Q. You note in the final conclusion of the publication that new materials are needed to lower the erosion rates; do you see that?
A. I do.
Q. Would you agree that science is always evolving?
A. I do.
Q. And since you have the paper in front of you, can you turn to the final section in this paper. I believe it's called the "Comment", which is where it's quoted from in your report.
A. Oh, in the paper.
Q. Sorry the publication. The third to last page begins a section called "Comment". Do you see that?
A. I do.
Q. Were you aware that the authors of this study use Mersilene almost exclusively in abdominal sacral colpopexy?
A. Well, they described a large number of them. If they were -- well, they use

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some other meshes, as I understand it, I think at least four, so it's not exclusive. But they used Mersilene in large volume.
Q. Okay.
A. Specifically for that procedure.
Q. Do you recall reading that in the comment that, "We use Mersilene mesh almost exclusively in our vault suspensions and cannot comment reliably on the erosion rates of the other materials"?
A. Where is it? I mean, it sounds like I've seen it before but can you point me.
Q. Same page where it has "References".
A. Yes.
Q. So that at least in the year 2000, we have -- approximately seven of the authors are all surgeons, Duke surgeons, who are using Mersilene mesh almost exclusively in vault suspension surgeries; is that correct?
A. That's what it says.
Q. Did that factor in your opinions in this case at all?
A. No.
Q. After reporting the results of

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this, their study, do the authors say that they're going to stop using Mersilene?
A. I don't know what they said after. I mean, there is a conclusion in the paper that new materials are needed, but if they stopped using it, if they started using some other mesh, I don't know.
Q. Have you seen papers previously that they'll state right out that because of the results of this study, they've ceased using that material at the institution?
A. I may; I don't recall specifically. Usually it's for drugs or treatment approach or some other. Some studies are terminated earlier.
Q. Do you have any criticism of these Duke surgeons decision to use Mersilene mesh almost exclusively in their vault suspensions?
A. I don't know what's their rationale for using it exclusively.
Q. I think that in the comment section they tell us part of the rationale. Give me two seconds and I'll find it.
The last paragraph:
"In conclusion, both abdominal

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sacral colpopexy and abdominal-only sacral colpoperineopexy appear to have a relatively low comparable rate of vaginal mesh erosion."

Do you see that?

A. Yes, but they compare Mersilene to Mersilene.

Q. The authors of this paper felt that the rate of erosion was low, correct?

MR. HAIL: Objection, speculation.

THE WITNESS: I don't know what's low and what's high, how they scale anything.

I think we saw that the length of the study was insufficient to detect long-term rates of complications. That "low" can be relative. If they have done the study twice as long, and maybe it would not be as low.

BY MR. SNOWDEN:

Q. Would you disagree with their statement that it's relatively low?

A. I would disagree with "relatively low". I mean, relatively low for that timeframe, maybe. But not overall for the device itself. But I also have to remind you that they are comparing Mersilene to Mersilene. Partially, that sentence

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refers to slightly different procedures using Mersilene.

Q. Do you recall reviewing a 2004 study by Nygaard entitled, "Abdominal Sacral Colpopexy: A Comprehensive Review"?

A. I remember his name. His or her, the name of the author. I remember the name.

Q. Okay. Do you recall that article?

A. I don't remember now. If you put it in front of me, maybe I will remember it.

Q. I don't have it.

A. But the name is familiar, yes.

Q. Doctor, if you can go to the first page of your supplemental report.

A. Yes.

Q. The second paragraph, second sentence:

"Although it can be partially dependent on surgical technique, the mesh itself is a major factor in the early mesh exposures."

Do you see that? Second sentence, it's the first page.

A. First page, you said second page.

Q. It's the second paragraph.

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A. "Although it can be partially dependent on surgical technique, the mesh itself is a major factor in the early mesh exposures."

Yes.

Q. And then you state: "Presence of foreign body in the wound is a known cause for retarded healing." Do you see that?

A. I do.

Q. Then you cite to the Robbins and Cotran Pathologic Basis of Disease?

A. It's a pathology bible, for residents at least.

Q. In that section on tissue repair, it actually lists nine factors; do you recall that?

A. Oh, there are multiple factors which can affect healing, yes.

Q. You agree those factors are infection?

A. Infection, yes.

Q. Diabetes?

A. Diabetes. Diabetes controlled and not controlled: That's a big difference. When somebody has well very controlled diabetes, there may be no difference at all.

Q. Nutritional status?

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A. Yes. Somebody is well nourished.

Q. Use of steroids?

A. Yes.

Q. Mechanical factors?

A. Mechanical is similar to foreign object. I mean, there is a mechanical separation of the wound, yes.

Q. Poor perfusion?

A. Yes.

Q. Type and extent of the injury?

A. Yes.

Q. And the location of the injury?

A. Yes.

Q. Okay. And in terms of foreign --

A. Location, it depends. I'm not really sure what -- I would have to see what exactly they meant by a location but -- because location may be referring to specific other factors, like perfusion status or...

Q. And the foreign bodies that they list in that textbook as examples are steel, glass and bone; does that sound right?

A. Well, foreign bodies are any foreign body. It can be steel, bone or something else. I mean, they may just cut the list shorter

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because it's impossible to list all possible foreign objects.

But the effect is not limited to steel, glass or bone. These are more common, but it's not limited to...

Q. On page 4 of your report?

A. Yes.

Q. I believe you're discussing here complications with a multifilament polyester mesh; is that right?

A. You mean in the second paragraph?

Q. Yes, sorry. The citation number 27 --

A. Yes.

Q. -- of that paragraph?

Do you recall how many people in that study had been implanted with Mersilene?

A. I don't think this part is -- I don't remember exactly what type of polyester multifilament mesh was there, Mersilene or other.

They specifically called it multifilament polyester, what I see in the quote, which is the same as Mersilene design.

Q. Well, I'm not trying to trick you. I'll represent that Mersilene was one of the

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polyester multifilament meshes used in that study. And I just simply want to know, do you know how many patients had been implanted with Mersilene in that study?

A. I didn't pay attention because polyester multifilament is polyester multifilament. And it can be called Mersilene; it can be sold by different brand names.

So the main feature is multifilament polyester. I mean, the main feature is multifilament; polyester is secondary. But Mersilene is one of the names for multifilament polyester mesh.

Q. Okay. So, if there were 32 patients who were implanted with Mersilene mesh in that study, is that sufficient number for you to accept conclusions regarding complication rates?

A. I would have to see the paper. Again, as I said, I mean there might be higher or lower quality of data.

Thirty-two patients may be sufficient number, depending on what feature we are talking about. If we simply aiming to establish a fact it can happen, 32 is a sufficient number.

Q. Doctor, let's turn to your

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case-specific report for Ms. Berden --

A. Yes.

Q. -- if you would.

We've already established that she's been implanted with Mersilene mesh through abdominal sacral colpopexy, correct?

A. Yes, that is my understanding.

Q. Is that a transvaginal approach?

A. No, it is not transvaginal approach. But we had a larger group of devices and they sort of are united with this designation of transvaginal devices. But some of them we know, we understand that they are not placed transvaginally. They do include vaginal area, vaginal wall, but not specifically transvaginal placement approach.

So maybe it's not very precise definition of transvaginal meshes, but like Gynemesh PS, we know that they're not placed transvaginally. Some of them are, but some them are not.

It's within the same group, because the bulk of the devices is transvaginal.

Q. And for this report, I've noticed that you copied and pasted the entire records themselves into your medical summary; is that

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right?

A. Yes. I mean, lately some records were coming in the poorest kind of quality, at least my text recognition didn't. And I just realized, I don't have to do text recognition, I can just take picture of the -- it's easier.

Q. Okay. Save time is that --

A. But it doesn't save space. Sometimes it saves time, yes.

Q. Did you review any case-specific depositions for Ms. Berden's case?

A. No.

Q. Have you spoken with anyone outside of counsel for Ms. Berden regarding your opinions in this case?

A. No, I have not.

Q. Have you reviewed any expert reports --

A. Expert reports, no.

Q. -- in this case?

A. No.

Q. You know this line of questioning.

All right. So we talked a while about the supplemental report. Is it fair to say that supplemental report discusses Mersilene, but it

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does not specifically address Ethibond?
A. Well, there is a relevance of Ethibond and Mersilene. So we know that multifilament sutures preceded multifilament meshes, at least for a short time.
And the amount of multifilament sutures that is used is larger. I mean, they used -- but the studies, many studies, studied the effects of monofilament versus multifilament design, based on sutures.
So in a way, Ethibond is similar thread or fiber type as Mersilene. It's multifilament, and it's polyester.
So there is some similarity between Ethibond and single fiber in Mersilene mesh.
Q. Have you told anyone at St. Michael's Hospital that Ethibond is harming their patients?
A. No, I didn't.
Q. Do you know if it's used at St. Michael's Hospital?
A. You asked me that question and I think I said -- I answered that, yes, they are used. And it's single suture. You cannot compare one single suture with mesh -- much larger, the

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volume of material is many fold larger.
Q. I think I asked about Mersilene but you probably answered about Ethibond, but we can move on.
A. You did ask about Mersilene and I answered that I don't know.
Q. Okay, fair.
A. And then we went on discussions with the old surgeon who was retired, who was surprised they were still out there.
Q. Okay. Are you aware that concurrent hysterectomy at the same time as implantation of an abdominal sacral colpopexy mesh carries heightened risk of mesh erosion?
A. I'm aware of reports that concurrent procedures may increase risks.
Q. Okay?
A. It's not that all risks is specific for hysterectomy. If there is a hysterectomy, there's no mesh implantation, there's no risk of mesh erosion.
But if there are several other procedures done in the same time, yes, it may increase -- may alter risks specific to the mesh.
Q. Are you aware that smoking has

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been shown as a risk factor for mesh erosion in -- when a mesh is placed in abdominal sacral colpopexy?
A. I am aware, again, of reports of smoking affecting rates of erosion.
Again, this would be factor which modifies the risks. It doesn't introduce it; it doesn't eliminate it. There a risk specific for mesh because this is the main factor.
Then there are some other factors which can change that risk either higher or lower. To me, smoking doesn't have significant effect -- to me, as a pathologist, it doesn't have significant effect in terms of tissue quality. It's indistinguishable to me.
Tissue of a non-smoker versus smoker will look exactly the same in the microscope. Smoking does not change tissues to a degree that would be detectible microscopically.
Q. Is obesity a risk factor for mesh erosion when a mesh has been placed with abdominal sacral colpopexy?
A. I don't know. I would have to ask urogynecologist. I am not aware.
Q. Are you aware whether diabetes is

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a risk factor for mesh erosion when a mesh has been placed via abdominal sacral colpopexy?
A. I think we discussed it. Diabetes, especially poorly controlled diabetes, is a risk factor for poor healing. When it's well controlled, people live normal lifespan and they don't have any complications.
It's the degree of control which has major effect. Again, it will modify risks which are specific to mesh, but it will not introduce them. The main factor in mesh erosion is mesh itself.
Q. If you can turn to page 25 of your report, you have a "Summary of Pertinent Records" section?
A. Yes.
Q. For all the records that precede at page 25 in your report, are those the records you deemed pertinent for your case-specific opinion in this case?
A. I thought that they are pertinent enough to be copied. But since I was copying entire pages, sometimes maybe if I saw something in very small, one line, I would -- I didn't copy.
Again, the copies of the pages is here

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to sort of put in chronological order for me to organize summary. The records speak for themselves. So I was aware of everything which was in the records.

Q. Do you recall anything else from the records that you didn't include that is pertinent to your opinions in this case?

A. Well, as I said, I mean I looked at all records. I include part of them in the summary, or copies of the pages. Obviously, I couldn't copy everything.

Q. Ms. Berden underwent a revision of her Mersilene mesh in August of 2004, correct?

A. 2014.

Q. Sorry.

A. You said 2004.

Q. Yeah, it wasn't a trick.

Were there any cultures done with the mesh at that time?

A. I don't remember now.

Q. Okay.

A. Probably could -- probably they were done, but I don't remember now.

Q. If they were done, is that something you would have put in your report?

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A. No, not really. I saw bacteria right there, I mean, it was filled, soaked with bacteria.

Q. So for purposes of your opinions in this case, are positive culture necessary?

A. No.

Q. Unnecessary?

A. Unnecessary.

Q. When you received the specimen in this case, was it fixed in formalin?

A. (Witness reviews document).

Judging by the quality of the -- at least debris which was residual, it was fixed in formalin at one point of time. I don't remember if it was filled with formalin totally, or drained. But you can see that neutrophils are there.

If it was left unfixed, the neutrophils would autolyse. Then it would have overgrowth of bacteria and everything else. But in the -- you can see clearly that there was some fluid left on the mesh.

And then, for example, page 32 and page 33 you can see neutrophils. They are preserved; they are not autolytic. You can have bacterial perforation if mesh is left unfixed, but

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the neutrophils would just autolyse.

Q. On page 32, to your CB-4, are there neutrophils that you can identify and circle on this image?

A. Well, the entire part, this part, is combination of inflammatory cells -- some of them are neutrophils, debris and bacteria, all together, this whole purple sort of area.

Q. The purple kind of half-moon at the bottom?

A. Yes. It's a combination of debris, inflammatory cells -- most of them are neutrophils -- and then bacteria. That's pus. That's how pus looks under the microscope.

Q. And are those, the dark purple kind of round structures, are those the inflammatory cells?

A. Nuclei of inflammatory cells but then you see sort of, well, there's a high magnification of this on page 33. Then you can see the pink cytoplasm.

Q. You make a statement in your report that Mersilene mesh showed no surface degradation, which was in keeping with material other than polypropylene. Do you recall that?

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A. Yes, I do. That's how I -- one of the ways of distinguishing between polypropylene and polyester.

Q. Are you aware of the chemical compatibility of Mersilene to formalin?

A. No, it wouldn't have any significance to my opinions here in this case. So, basically it's a multifilament mesh. I know that it was Mersilene from the records.

From what I see, it's not polypropylene, because by that -- by three years in the body there would be a degradation layer, like I see in other multifilament polypropylene meshes like ObTape. It's consistent.

It's multifilament. It has no features of polypropylene, at least those that I am aware of, and the record says it's Mersilene.

Q. Are you aware if Mersilene is chemically compatible with alcohol?

A. It's not dissolved. From what I see, it's been through alcohol, it's been through xylene, formalin and the fibers are there, preserved. At least preserved enough to stay on the slide.

Q. Are you aware if Mersilene is

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chemically compatible with xylene?
A. Again, compatible enough to be preserved on the slide. It went through these stages and it's on the slide.
Q. Have you done any chemical testing of Mersilene?
A. No.
Q. Have you reviewed any literature that discusses the chemical resistance of Mersilene?
A. No, I don't think it would be relevant in this case. I don't see degradation layer on the surface. So if there are other changes, degradation or other changes of the polymer through any other process, I cannot detect it microscopically.
And I perfectly accept that there might be changes of -- sorry, of polymer over time, which may not be detectible by microscopy. They might be detectible by other means, but not by transmission microscopy.
Q. In your report, in the pathological findings, you note that "the spaces were large enough to accommodate shelter bacteria"; do you recall that?

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A. Which page?
Q. Page 26, second to last paragraph.
A. Yes.
Q. Did you measure those spaces?
A. They ranged from almost no space when they were touching, to a larger spread, 15 microns or more.
Q. The image on -- let's turn to page CB-9 on page 37.
A. Oh, they're in there upside down.
Q. Do you see that Figure CB-9?
A. Yes, I do now.
Q. These fibers appear to be split apart somewhat; is that fair?
A. Yes, but it's not what was in the body. I mean, because -- there is no tissue which supports it. So we don't know how far they were. But to answer your question, yes, in this specific slide, they are split apart.
Q. Okay. Is this an example of kind of what can happen with the microtoming process in terms of disrupting how it had looked in the body?
A. It's not just microtoming. It's just because the fibers are not supported by the tissue because it was floating in this purulent

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exudate.
If it's not supported it can move through multiple means, if there is no sort of matrix which would hold it together.
Q. And if we turn to CB-7 on page 35. Is it your opinion that these fibers shown here are more spread out than they would have been in vivo?
A. They may or may not. They may be exactly where they were in vivo or maybe a little bit spread out. Unlikely they are closer to each other. But again, they can move if they're not supported.
Some of them are almost touching, so I guess there cannot be smaller space than that. And some of them are slightly further apart.
Q. Are the gold colored flecks in here, is that hemosiderin?
A. No, probably not. It's some other degenerative pigment. Or maybe it's part of the dye for whatever reason because it's -- no. It's H&E.
So it may be some other -- because many pigments form during degradation of biological materials. Like when tissue rots, it can produce different pigments and just products of degradation

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of biological material.
Q. Fair to say in this specimen there's no mucosa; is that correct?
A. That's correct.
Q. In this case, you did not find any fibrous connective tissue; is that fair?
A. Not in a way we saw in other photographs. I mean, there might be some remnants of it which are sort of masqueraded within the purulent material, but nothing well-formed.
Q. Essentially, the specimen you have in this case is a mesh surrounded by purulent material with some neutrophils, and in your opinion bacteria; is that fair?
A. Yes.
Q. Okay.
A. The debris is a combination of necrotic tissues, whatever was preexisting there. And we know it would be mostly fibrous tissue.
Q. I'm just trying to pin down, so at trial you don't come in and say you found nerves and all sorts of other things in this specimen. Is that fair?
A. It's fair, correct, yes.
Q. Okay.

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A. But I will not testify that I found nerves. At least not in this specimen.
Q. All right. My understanding of your opinion in this case is that you're not able to tell whether this was -- the infection occurred first or whether the erosion occurred first; is that correct?
A. That's correct. I don't think I can pinpoint which was initial.
Q. And would you also agree that in this case, you didn't have any tissue on the mesh to be able to determine whether there were any effects from uncontrolled diabetes in the tissue?
A. I don't think in this location even if you have tissue you would be able to see the effect of uncontrolled diabetes or controlled diabetes. Even if there was tissue, it would be difficult.
I mean, mostly for uncontrolled diabetes you would need peripheral tissues. And it's a clinical diagnosis; it's not histological diagnosis. I mean, you can have some findings and with clinical history you can interpret that.
Q. And in terms of, in this case, there's no tissue for you to be able to determine

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whether smoking had effects on Ms. Berden's issue; is that fair?
A. I told you before, you can give me a whole body, and it would be difficult who is smoker, who is not smoker. I mean, the changes in tissue are mostly oncogenic effects like lung cancer, and still nonsmokers can develop lung cancers.
You can examine lungs, you can see pigment, but sometimes other sources of pigment like working with oven, inhaling smoke of other origin, will give same effects.
Q. On page 28 of your report, in the first full paragraph, you have an opinion regarding --
A. It's a signature page, yes.
Q. Yes, the signature page.
You have an opinion regarding that:
"Residual tissue damage and scarring caused by the mesh, infection, subsequent surgeries continued and continue to pose a risk for pain and other associated symptoms for Ms. Berden."
Do you see that?
A. I do.

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Q. Is the basis for that opinion your general reports in this case?
A. Well, the basis for this opinion, my knowledge, training and experience and my experience in research in mesh -- in the field of implantable meshes.
Generally, the report summarizes those opinions to a degree, but my knowledge is a bit broader than just the report.
Q. And I think my point really is, you haven't seen any tissue from Ms. Berden that is still in her body that you're going to opine about; is that fair?
A. Should have asked that first time.
Yes, I have not seen -- you're correct, I have not seen tissue beyond what I've seen in the specimen.
So if I'm opining on factors such as inflammation -- foreign body type inflammation or, in this case, scarring, residual scarring or residual nerve damage, that would be based on my general understanding, general knowledge.
Q. What's the significance for your opinions of the gross pictures you include in your report, your CB-1 through 3?

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A. Can I run to washroom quickly?
-- RECESS TAKEN AT 3:17 --
-- UPON RESUMING AT 3:22 --
-- Reporter's Note: Whereupon, the question was read as recorded above.
THE WITNESS: Documentation showing what exactly what I received, what state, and showing that it was covered -- the mesh is consistent with Mersilene mesh, that it's covered with purulent exudate, how grossly it looks, then I show it microscopically.
BY MR. SNOWDEN:
Q. Have you ever seen a pristine Mersilene mesh?
A. Yes, I did. I have a sample.
Q. Do you have that in your lab?
A. In my office. I've had it for many, many years, at least from 2013. Dr. Ben David brought it to me, he brought his whole collection of different types of meshes.
Q. Have you done any testing or analysis on pristine mesh?
A. No, I haven't.
Q. Figure CB-4, what is the significance of this to your opinions in this case?

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A. CB-4 is a microscopic section of what we saw grossly in previous images, and it shows part of the mesh and then purulent material, it's bacteria, debris.

Essentially, that's how pus looks grossly on previous images, and that's how pus looks microscopically.

Fixed pus, not autolytic tissue which is necrotic through autolysis. So this is tissue which was purulent and then was fixed by formalin.

Q. With autolysis, do you lose tissue cellularity in the tissue?

A. You lose everything. It becomes one homogeneous, pink, amorphous material. You can have bacteria proliferating, but if it's pure autolysis it becomes pink.

And if everything is pink, homogenous, have some ghost sort of contours of what was existing before, to a degree. After a while, it all becomes lost, lose matrix.

Q. Okay. So that includes like -- you lose fibroblasts in autolytic tissue?

A. If they were there. Anything, I mean -- well, bone will keep a structure, cartilage will keep some structure to a degree. But with

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time you lose all details. Either mummifies or it disintegrates, liquifies and it's gone.

Q. CB-5, what is the significance of what we see here to your opinions in this case?

A. It's magnification, it can have some preservation of tissue, so it's dried up. But if it remains wet, it will be -- sorry. That's professional --

Q. Let's come out of the rabbit hole. That was my fault.

What is the significance of what you see in CB-5 to your opinions in this case?

A. It's a higher magnification of similar area, looks different. It's the same, it's part of mesh, and then there is this fibrinopurulent exudate on the surface of mesh. It's essentially how pus looks at high magnification.

Q. And is there -- turning to CB-6, anything new that you haven't already discussed about CB-4 and CB-5?

A. CB-6 is more focusing on interior sort of compartments within the mesh, and, mostly, it is bacterial proliferation between the mesh fibers.

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Q. Is the bacteria -- where is the bacteria here?

A. This sort of smaller --

Q. Circle it so we can save it for posterity.

A. I will circle some representative clumps of bacteria, it doesn't mean that it will be limited -- bacteria will be limited to the circled areas.

Q. That's fine.

A. So these are larger clumps.

Q. Is that pen showing up?

A. Yes, it is showing up.

Q. Okay. So you circled that in yellow highlighter?

A. Yes. I mean these are clumps of bacteria with debris together and with other particles. But mostly bacteria.

Q. And what's the basis -- I think -- what's the basis for your opinion in this case that the mesh was infected?

A. Clinical history. So the descriptions of infection in the mesh. And then examination, gross examination. Clearly it was covered with pus.

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And then microscopic examination. I can see the most features of infection, pus, purulent exudate, which is extreme degree of acute inflammation.

And the bacteria, which we talked many times and we don't see bacteria as often. So in most cases there is mesh erosion, there is a degree of infection, but we only see neutrophils as reacting to those bacteria. So if bacteria are clear, they don't grow in such big numbers. In this specific case, we see a lot of them, large colonies of bacteria.

Q. Okay. CB-7, if you turn there.

A. Yes.

Q. Could you circle -- is it your opinion there's bacteria in CB-7?

A. They're mixed in between mesh fibers. They are mixed with other, some amorphous particles and amorphous material.

Q. Can you circle representative areas of bacteria?

A. I can circle representative area, one. I circled one but it doesn't -- it's not limited to only one.

Q. So you circled that with the

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yellow highlighter?
A. Yes.
Q. Anything different about the significance of what's depicted here from what you've already told us?
A. This is more compact and it shows size of bacteria and size of the spaces. And it demonstrates the fact which was known before and was studied before in hernia meshes and studied, and those studies were used for classification purposes.
The spaces between filaments and multifilament design were too small for cellular traffic. Neutrophils cannot clear bacteria from these areas. So bacteria relatively sheltered in these spaces.
There's no tissue ingrowth, there's no matrix where the neutrophils can move around, and that's why this mesh is classified as class 2 or class 3.
(Reporter sought clarification.)
Class 2 or class 3. Specifically for Mersilene, it's class 3 because of these factors, because these factors predispose meshes to infection.

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Q. CB-8 looks like Gram staining of the mesh?
A. Yes.
Q. Why did you use Gram staining in this case?
A. It's just habit, professional -- I didn't have to. Every time I think about bacteria I just use Gram stain. It's not relevant in this case, at least not relevant to my opinions.
But sometimes we do it for other bacterial conditions like bacterial endocarditis, professional reflex.
Q. In this case, the Gram staining didn't pick up any Gram-positive bacteria, did it?
A. It's sort of red, so I didn't see any purple bacteria in there. It may or may not reflect what was in the cultures so it may or may not reflect what was in the entire mesh.
Maybe the stain doesn't work well within the spaces in between fibers; I don't know. But most of the material was red or orange color.
Q. Which is Gram-negative?
A. Yes.
Q. Why did you use polarized light in CB-8?

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A. Just to show where the fibers are. Again, it's professional habit, reflex. There is foreign object, you use polarized light.
Q. Is there any additional significance for purposes of your opinions in what is shown in CB-9?
A. It's a high magnification, again, Gram stain. Bacteria appear orange. I don't see purple or blue color bacteria. May or may not reflect Gram positivity or Gram negativity, because I never studied if Gram stain works well in the presence of mesh, or specifically polyester mesh.
They appear Gram-negative. Again, it will be subject to the validity of the Gram stain, and I don't think it's relevant.
I mean, the main feature here is that there are bacteria, they would stain with any stains.
(Reporter sought clarification).
A. There are bacteria, with any stain. You can see them with any stain.
Sometimes we get bacteria in endocarditis samples, like the leaflets from the lab. And you check with the cultures, and the culture says Gram-positive, but your stain shows

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different.
So then we report it, and just to contribute to the treatment plan. So sometimes cultures do not perfectly correlate with the microscopic appearance.
It's a sampling issue, where you took the sample. Also may be issue of where bacteria grow better, because there might be different media for culture.
I mean, if you do PCR, maybe it's a different story. The bottom line is, there may or may not be correlation between histological Gram stain and cultures.
Sometimes they are contributory. Sometimes they correlate; sometimes they don't.
Q. We've discussed that there's no segment, no portion of mucosa in this specimen. Would you agree with me that this specimen does not contain the site of mesh erosion?
A. I would agree that there is no mucosa, but when there is a large erosion, there's no mucosa because mucosa is necrotic. You can only see mucosa at the edges, viable edges, for any erosion.
So if you excise part which is eroded

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already, they will be never, um, an erosion. I think we had a case like this yesterday or sometime. I mean, we discussed it.

Q. Would you agree that you don't have a site of the mesh eroding through Ms. Berden's tissues in this case?

A. That's what I told you. We might be looking at the erosion, at the ulcer bed, but because the ulcer bed was composed of mesh, that's how it looks.

There may not be any tissue left at the ulcer bed. It may be just mesh with pus. And the only way to actually see the tissue is to see where it is still preserved. This will be edges and maybe bottom, deeper than the mesh.

Q. Okay. So you have the mesh that has eroded, but not the -- where it meets the tissue essentially?

A. Yes, there is no transition point with the viable tissue.

Q. Is it fair to say that you will not be offering any opinions in this case regarding Ms. Berden experiencing pain, based solely on your review of the mesh specimen?

A. Not solely. As I said, it's

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combination of multiple pieces of information. Based on the specimen, I can say that there was mesh, Mersilene. I can confirm it was infected. There was focus of infection, that I can show.

But then the rest will be coming from records, from my general knowledge.

Q. Okay. And is that true for any other associated symptoms outside of the infection itself?

A. Yes, for associated symptoms, yes. For infection, I can show it; I can show what's the cause for infection; I can identify mesh. For associated symptoms, this would be based on general knowledge.

MR. SNOWDEN: I'm just going to take a look at my notes here.

BY MR. SNOWDEN:

Q. When you processed the tissue -- when you processed the mesh to create slides, did you use the standard procedures that you always use in creating pathology slides?

A. Yes, the procedures are standard. They are not just standard for St. Michael's Hospital laboratory. They are standard throughout North America or entire world.

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Because the machines and the chemicals are bought from the same suppliers, and the same protocol has been used and the same approach has been used for a hundred years so...

And this is the best way to do microscopy.

Q. If you can turn back to your supplemental report in this case, please.

On page 11 of the report, you have a section that begins "for mid urethral slings"; do you see that?

A. Yes.

Q. Is it fair to say this section is based on your review of ObTape mesh?

A. Yes, this is the only polypropylene multifilament mesh which was -- which I am aware of used in vaginal locations.

Q. The vaginal location this was used in is different than the location Ms. Berden's mesh was implanted; is that fair?

A. Yes and no. I mean, it's not specifically the same location. But it's the same environment, the same vaginal wall, the same risks for erosion, because we know that both pelvic organ prolapse meshes and slings can erode. They are

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affected by the same mesh-body interactions.

Q. Are there any differences between ObTape mesh and Mersilene mesh that are important for your opinions in this case?

A. There are similarities and there are differences. Mainly, the similarities, which are important to me. Similarities, multifilament design. There are differences, of course.

It's a different material, different polymer. It's a different weave, but what is important to me is the similarity. And similarity is multifilament design, and higher risk for infection.

Q. Okay. Do you recall what the overall risk of infection is with ObTape?

A. So I compared the reasons for excision for ObTape and reasons for excision for other slings, of monofilament slings, and the difference was significant.

Most of the ObTape slings in my data set were excised for infection and/or erosion, while monofilament meshes, they have much lower rate of erosion. I don't remember exactly, but we can go to the abstract. There was a study.

Q. Your study?

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A. Yes, my study. There were also other studies. I mean, I just supported what others -- because you see there are so many references.

So some of them were just reporting ObTape. Some of them were comparing with other designs.

So it supported the overall understanding of multifilament design prone to be -- prone to infection, which was established with hernia meshes.

And then when the multifilament designs were introduced to vaginal locations or pelvic locations, they showed the same pattern.

Q. That abstract of yours that you referenced, was that looking at ObTape compared to monofilament meshes or did it also include Mersilene?

A. ObTape compared to monofilament. I am not aware of Mersilene slings.

Q. Okay. So you were just looking at slings because ObTape -- okay?

A. I was looking at slings to compare, as close as possible, apples to apples. This is the same vaginal location, but for clarity

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of comparison, we compared exactly the same locations, for the same designs.

It does support what was learned decades before based on hernia meshes, so these things didn't improve when the design was used in the vaginal location, when it was moved from hernia to pelvic surgeries.

Q. And do you know whether the risk of erosion is higher with ObTape than with Mersilene mesh implanted in abdominal sacral colpopexy?

A. I did not compared ObTape with Mersilene for colpopexy. I did not have those samples in my analysis. As far as I know, there was no comparison between them.

Q. And same question for, with regard to infection, is it the same answer?

A. It's the same answer. One of them may be better; one of them may be worse. But they do belong to the same group of meshes by classification, class 3.

Q. On page 3, you note that the earlier reports of infections associated with multifilament mesh, Mersilene, date back to at least the 1970s; do you see that?

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A. I do.

Q. And that study was in chin implants; is that true? Do you recall?

A. (Witness reviews document). Yes.

Q. Does the location of the implant have any significance to your opinions in this case?

A. Not specifically for this statement.

Q. Why not?

A. Well, chin is not a specific location which would become more exposed or less exposed to infection than any other sites.

There may be some variability between them. It's deeper in the tissue.

Q. If I understand this paragraph, is this sort of you're setting out the historical history of when it was noted Mersilene, that there were infections associated with Mersilene; is that fair?

A. Yes, just historically. It could have been another location, it just happened to be chin. So it has no specific significance.

MR. SNOWDEN: That's all I have, thank you.

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THE WITNESS: Thank you.

MR. HAIL: Can we take a quick break?

-- RECESS TAKEN AT 3:48 --

-- UPON RESUMING AT 3:53 --

CROSS-EXAMINATION BY MR. HAIL:

Q. Doctor, you've mentioned several times during this deposition a classification system for meshes; do you recall that testimony?

A. I do.

Q. Can you describe that classification system?

A. So after several decades of different designs used for hernia surgery, there was enough data to classify meshes. And the main criteria for classifications were tissue ingrowth and infection.

And based on the risks of specific mesh designs, the meshes were classified as class 1, 2 and 3: Microporous, macroporous -- sorry, macroporous, microporous, and mixed designs.

So these were the main sort of -- first three groups of synthetic meshes. And because of the porosity, or spaces within the mesh, were crucial for tissue ingrowth and infection, this became the main factor to classify them into

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different groups.
And the surgeons would know which type to use and which type can lead to specific complications, mainly, infections.
Q. In the classification system, where does Mersilene fall?
A. Mersilene falls into 3. It is a mixed design. It combines both larger pores and smaller pores. But the drawbacks of infection are specific for the microporous component.
Q. You've mentioned also, there's been testimony you've given about monofilament meshes; do you recall that?
A. I do.
Q. In the classification system, where do monofilament meshes fall?
A. Monofilament fall into class 1. So it's the first group of devices which have larger spaces only, they don't have smaller spaces.
Therefore, they show better tissue ingrowth and lower risks of infection. Not that they are totally immune to it, but they showed it lower, significantly lower enough to be in a separate group from other designs.
Q. In your practice as a pathologist,

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have you had the opportunity to examine class 1 monofilament meshes?
A. Yes, I examined a large number of them, several hundred.
Q. And as a pathologist have you had the occasion to examine class 3 multifilament meshes?
A. Yes, I examined class 2 and class 3. And I observed exactly what was described in the published literature, for microporous components and for propensity for infection and limitations of tissue ingrowth in multifilament designs.
Q. Based on your reviews of explanted mesh samples, as a pathologist, have you drawn any conclusions about the -- whether one classification of meshes is less prone to infection than another?
A. Yes. My observations of, in my practice, just confirmed what was well-known in published literature, that smaller pores, specifically in multifilament designs, are more prone to infection.
There are smaller spaces, less cellular traffic. The spaces can provide shelter from bacteria, exactly what was described for decades.

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I confirmed that.
Q. As a pathologist, have you sought to educate yourself on the professional literature regarding meshes and the different types of meshes that fall in the classification system?
A. Yes, I did.
Q. Have you found or come to any conclusions regarding your review of professional literature as to how class 3 and class 1 meshes operate as to infection and erosion?
A. Yes, and I explained that smaller spaces, they provide shelter for bacteria and less traffic. That was described in the literature and that's what I have observed in my examination of the samples I received.
Q. And have you operated -- have you yourself conducted any peer-reviewed studies that would address differences, infection and erosion, as to class 1 and class 3?
A. Yes, I had opportunity, I had similar devices, vaginal devices.
One group had multifilament design, class 3, and the other group of similar devices was monofilament.
And my observation, or my findings in

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that study were in line with all those published studies showing that class 3 will have higher risks for infection.
Almost all of those class 3 vaginal devices were removed for infection, and showed microscopic features of infection.
Q. Were you the first author of that study?
A. Yes, I was.
Q. And was that study published in the World Journal of Urology?
A. Yes, it was.
Q. And was that a peer-reviewed journal?
A. It was an abstract. I think it was peer-reviewed for the publication. Because some abstracts are reviewed by the committee, some abstracts are reviewed -- committee is the same peers; it's just a smaller group. And some of them are sent for peer review.
I don't remember exactly what was the review process but there is always a review process.
Q. And is the World Journal of Urology the type of journal that pathologists and

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professionals rely upon in their work?
A. Yes, it was also presented to the conference. So an abstract went to the journal and the presentation was presented during the conference.
Q. Who was the sponsor of that conference?
A. It was one of the urological associations. I don't remember exactly.
Q. It may be listed in your CV?
A. I can see in my CV.
MR. SNOWDEN: It's not part of the exhibit, I don't think.
THE WITNESS: It is.
MR. SNOWDEN: Oh, it is.
MR. HAIL: Yes, towards the end.
MR. SNOWDEN: I stand corrected.
THE WITNESS: It's International Society of Urology. Congress of International Society of Urology.
BY MR. HAIL:
Q. And when you presented your findings to the International Society of Urology, did anybody come up to you and say that your findings were wrong?

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A. No, because there was a long trail of similar publications showing the same fact. It wasn't something new. That comparison has been done several times before, mainly clinically. I just had opportunity to show it microscopically.
MR. HAIL: Thank you. That's all I have.
MR. SNOWDEN: I just have one quick question.
REDIRECT EXAMINATION BY MR. SNOWDEN:
Q. That presented abstract you're talking about, is that on page 12 of your CV?
A. I just had it open. Yes.
Q. Which one is it on there?
A. 2016.
Q. "The Reason why some Sling Designs Can be Prone to Infection"?
A. Yes, it is.
Q. Who were the other authors, if any, on that abstract?
A. I believe Dr. Blaivas, maybe somebody else, but at least myself and Dr. Blaivas.
Q. Would that be found somewhere on your CV as well?
A. Yes. I mean, the abstract should

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be listed in the abstracts as well.
Q. There it is on page 8, number one, Iakovlev, Blaivas J?
A. Yes.
Q. Okay. One quick question -- two more.
When you were asked about class 1 versus class 3 meshes, and your analysis of those, is that the same work that you and I had been discussing during my questioning, or was that something different?
A. Now I'm confused. I don't remember what we discussed.
Q. Just now you were asked about work you had done comparing class 1 and class 3 meshes; do you recall that?
A. Yes, now we were specifically talking about this study.
Q. Okay. And is that the same study that looked at ObTape in comparison to monofilament meshes?
A. That is correct.
Q. Last question. Are you offering any opinions in this case regarding the implanting surgeon's decision to implant Mersilene in 2011?

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A. No, I'm not discussing. I'm a pathologist. I'm showing what went wrong and the reasons or most likely mechanisms.
MR. SNOWDEN: All right. Thank you.
MR. HAIL: Thank you, Doctor.
-- OFF THE RECORD DISCUSSION --
THE REPORTER: Would you like a copy of the transcript?
MR. HAIL: We will want a copy. But I will have to get my people in touch.

-- Whereupon the deposition concluded at 4:04 p.m.

REPORTER'S CERTIFICATE

I, JUDITH M. CAPUTO, RPR, CSR, CRR, Registered Professional Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed at my direction;

That the foregoing is a true and correct transcript of my shorthand notes so taken.

Dated this 24th day of September, 2018.

_____

PER: JUDITH CAPUTO, RPR, CSR, CRR

CERTIFICATE OF REPORTER

CANADA)
PROVINCE OF ONTARIO)

I, Judith M. Caputo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand, using Computer Aided Realtime, to the best of my ability and thereafter reduced to written format under my direction; that I am neither counsel for, related to, nor employed by any of the parties to the action in which the deposition was taken, and further that I am not related or any employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

_____
Judith M. Caputo, RPR, CSR, CRR

Commissioner for taking
Oaths in the Province of Ontario

ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
[WITNESS NAME] DATE

Subscribed and sworn to
before me on this _____day
of_____,20___, by _____
_____,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____